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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–3028]

Medical Devices: Draft Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease.'' This draft guidance is intended to provide current insights on the design, data collection, and data analysis of studies that are important to the premarket approval application (PMA) approval process for in vitro diagnostic (IVD) devices pertaining to HCV. This draft guidance document represents the agency's current thinking regarding PMA's for IVD devices that pertain to HCV infection. This draft guidance is neither final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by (*insert date 90 days after date of publication in the* **Federal Register**).

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send

two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to provide recommendations for studies to demonstrate performance of assays for detecting evidence of infection with HCV. A meeting of the Microbiology Devices Advisory Panel was held on February 12, 1998, to obtain suggestions and recommendations from the panel regarding scientific information necessary for premarket approval of tests for hepatitis viruses. Following the panel meeting and subsequent discussions between FDA and representatives of the Health Industry Manufacturers Association (HIMA), HIMA developed a draft guidance document for tests to detect HCV and submitted it to FDA. This draft guidance document issued by FDA reflects modifications to HIMA's proposed document and, therefore, does not necessarily reflect HIMA's original or current position.

II. Significance of Guidance

This draft guidance represents the agency's current thinking regarding the content of PMA's for IVD devices pertaining to HCV. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR

8961, February 27, 1997). This draft guidance is issued as a Level 1 guidance consistent with GGP's.

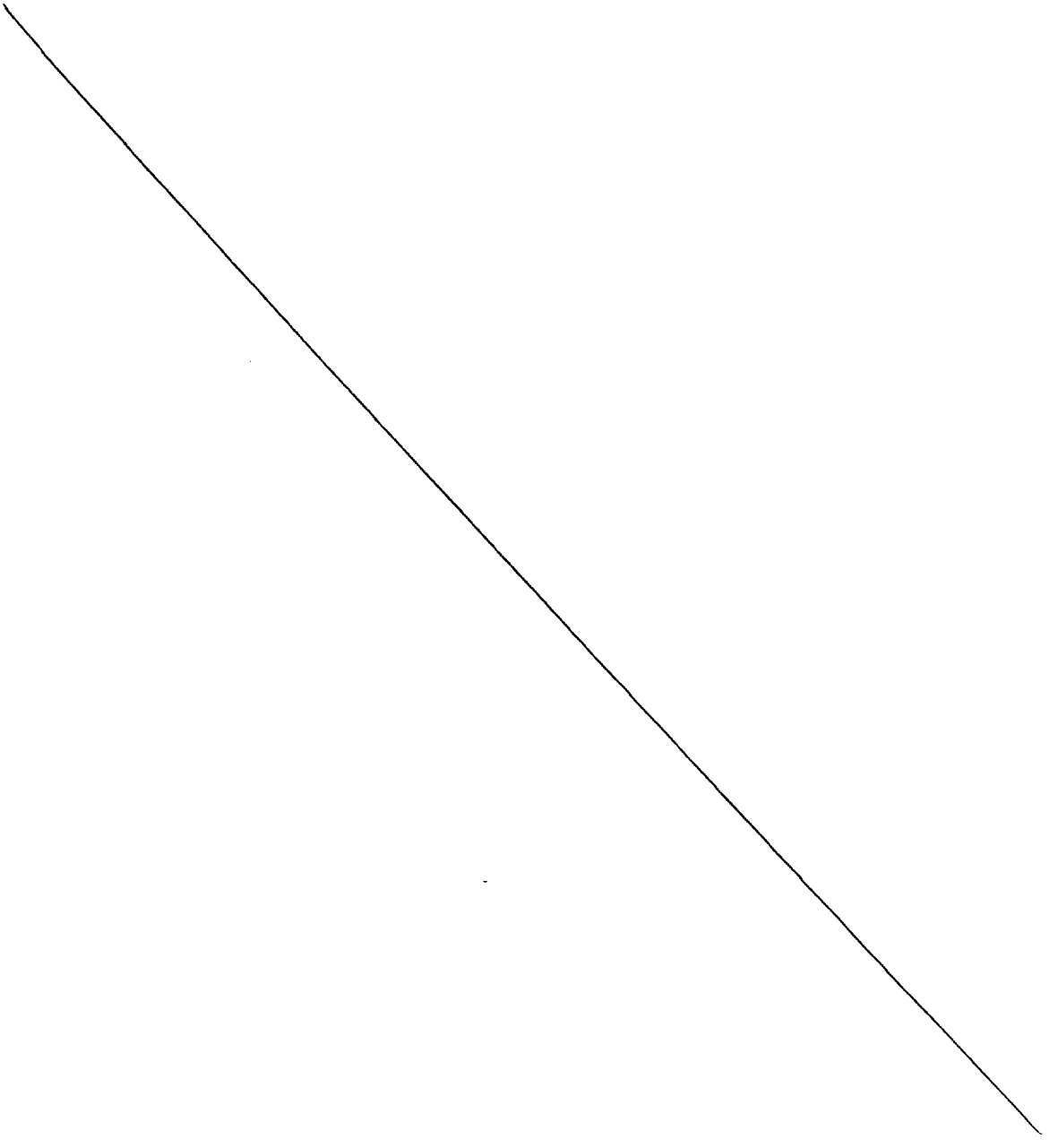
III. Electronic Access

In order to receive the draft guidance entitled ''Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (1353) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The ''Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis on Monitoring of HCV Infection on Associated Diseases'' will be available at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets



in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/13/99

September 13, 1999

Linda S. Kahan

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Regulations Policy
Center for Devices and
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